

<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional)  101672.0019P	
		Application Number  10/803,512	Filed  March 18, 2004
		First Named Inventor Guy Rome	
		Art Unit  3763	Examiner  Q. H. Vu
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="width: 60%;"> <p><input type="checkbox"/> applicant /inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>45,218</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____</p> </div> <div style="width: 35%; text-align: center;"> <p>_____ /Todd W. Wight/ Signature</p> <p>_____ Todd W. Wight Typed or printed name</p> <p>_____ (714) 641-5100 Telephone number</p> <p>_____ November 23, 2009 Date</p> </div> </div> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			
<p><input type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>			

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).

Dated: November 23, 2009

Electronic Signature for Todd W. Wight: /Todd W. Wight/

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Dated: November 23, 2009

Electronic Signature for Todd W. Wight: /Todd W. Wight/

Docket No.: 101672.0019P  
(PATENT)  
EFS WEB

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Guy Rome

Application No.: 10/803,512

Confirmation No.: 5437

Filed: March 18, 2004

Art Unit: 3763

For: MULTIFUNCTION ADAPTOR FOR AN  
OPEN-ENDED CATHETER

Examiner: Q. H. Vu

**ARGUMENTS FOR PRE-APPEAL BRIEF PANEL REVIEW**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicant respectfully submits the following arguments in support of the Pre-Appeal Brief Request for Review filed concurrently herewith.

Applicant filed a Notice of Appeal along with a Request for Pre-Appeal Brief Review on October 28, 2008, appealing the rejections maintained in a final Office Action mailed May 30, 2008 and Advisory Action mailed October 16, 2008. A Notice of Panel Decision from Pre-Appeal Brief Review was mailed February 18, 2009, indicating that prosecution was re-opened pursuant to the conference, that the rejection was withdrawn, and that a new Office Action would be mailed.

After a Restriction Requirement and Response, a non-final Office Action (hereinafter, "Office Action") was mailed July 22, 2009, rejecting each of the pending claims based on new

references.<sup>1</sup> Specifically, independent claim 30, the sole independent claim presently under prosecution, stands rejected under 35 U.S.C. § 102(b) as anticipated by USPN 4,512,766 to Vailancourt (hereinafter, “Vailancourt”), and by USPN 6,932,795 to Lopez (hereinafter, “Lopez”). Both Vailancourt and Lopez fail to show or describe features as recited by independent claim 30. Thus, Applicant hereby appeals and requests review of the Office Action by the Panel.

Independent claim 30 recites, *inter alia*, “a connector including a distal end attached to a proximal end of the catheter and a passageway . . . a proximal portion of the passageway including an engagement feature configured to connect an end of an instrument to the connector, a distal portion of the passageway including a valve having a closed proximal end with a slit and an open distal end, the valve proximal end distal of the engagement feature.

#### Vailancourt

The Office asserts that Vailancourt discloses a catheter 19; and a connector 10 including a passageway, a proximal portion of the passageway including an engagement feature 13. (Office Action, p. 2). However, the Office has misinterpreted the Vailancourt reference, as it does not include an engagement feature. Even if the asserted feature were for engagement, the passage does not include the asserted engagement feature as claimed.

Vailancourt discloses a catheter assembly including a valve surrounding an inlet end of a hollow elongated insert disposed in a hub. (Vailancourt, Abstract). The asserted engagement feature is described as follows: “The open hub end is surrounded by an annular flange 13 which extends radially outward to facilitate gripping of the hub during removal of a needle unit and during insertion and removal of a connector for a medicament administration set.” (Vailancourt, col. 3, ll. 45-48). Thus, Vailancourt merely shows and describes a flange on the external surface of the asserted connector to provide a hold to facilitate gripping. Accordingly, Vailancourt fails to show or describe an engagement feature configured to connect an end of an instrument to the connector.

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<sup>1</sup> Applicants acknowledge the claim objection to two claims being numbered as “41” and intend to re-number the second claim 41 to claim 42 as suggested by the Examiner.

Even assuming *arguendo* that the asserted flange could be an engagement feature, it is not included in the passage as claimed. Instead, the flange is shown on an external surface of the asserted connector to facilitate gripping. Thus, the asserted engagement feature does not connect to an instrument, nor is it included in the proximal portion of the passageway. Accordingly, the Office has failed to present a *prima facie* case in support of the rejection.

With regard to dependent claim 41, the Office asserts that Vailancourt also discloses a syringe adaptor 40. However, Vailancourt describes the asserted adaptor as a male Luer adaptor 40 from an administration set. “The forward end of adaptor 40 peripherally tapers to match the wall 15 of hub chamber 11 to provide a friction or interference fit engagement after the male adaptor has been sufficiently inserted into the chamber.” (Vailancourt, col. 5, ll. 28-34). Thus, the asserted connector is not a syringe. Moreover, the asserted connector does not slide over the connector housing but fits within the passage. Thus, Vailancourt does not show or describe the features as recited in dependent claim 41.

#### Lopez

The Office asserts that Lopez discloses a catheter assembly in FIGS. 8-9 comprising a catheter 416 including a connector 412, the proximal portion of the passageway including an engagement feature 470, and a distal portion of the passageway including a valve 418 having a closed proximal end with a slit 466 and an open distal end. However, Lopez does not show or describe the features as claimed.

Lopez discloses a positive flow valve which is utilized between a catheter and another medical implement. (Lopez, col. 2, ll. 43-45). The valve 410 includes a valve body 412, a flexible tubing 416 that may be connected to a catheter, and a seal 418. The asserted engagement feature 470 is merely described as an upper conduit. The Office may have intended the knob feature on element 470 to be the asserted engagement feature. This feature is not specifically described by Lopez, but a similar feature of FIG. 2 is describes as “a conventional Luer-Lock threads 240 on the outer diameter of the upper conduit 226.” (Lopez, col. 5, ll. 53-55). The conduit itself is not an

engagement feature, and the conventional Luer-Lock threads are on an outside surface of the conduit, and thus are not included in the passageway, as claimed.

Moreover, the asserted valve is not included in a distal portion of the passageway as claimed nor is it distal the engagement feature. As described, the tube 416 is connected to a catheter. Independent claim 30 recites “a connector including a distal end attached to a proximal end of the catheter.” Thus, the lower end of the figure, including tube 416, would be the distal end of the connector. As shown, the asserted valve is at the top of the figure, and thus at the proximal end. Further, the valve is flush with the end of the connector housing. The valve is opened when it is pushed into the housing. Specifically, “[t]he positive-flow valve 410 advantageously eliminates any dead space during decompression of the seal 418. This is further assisted by the seal 418, with the slit 466 remaining open until the very end, i.e., until the seal cap 460 is squeezed by the upper conduit 470.” (Lopez, col. 13, ll. 28-32, emphasis added). Thus, the asserted seal is not included in a distal portion of the passageway.

The Office has attempted to use FIG. 9 to illustrate a valve proximal end distal the engagement feature. However, “FIG. 9 shows the compressed state of the valve 410 upon insertion of the syringe 428.” (Lopez, col. 12, ll. 60-61). In this state, the valve does not have a closed proximal end with a slit. As described, the slit is an oval or elliptical shape that is squeezed shut by the circular opening of the upper conduit. (See, col. 6, ll. 31-35). Thus, as soon as the asserted valve is moved from the proximal end of the asserted connector, it no longer provides a closed end. Accordingly, the Office has failed to present a *prima facie* case in support of the rejection.

With regard to dependent claim 33, Lopez fails to describe the engagement feature as an o-ring. First, the asserted o-ring 420 is between claim shells 422a/422b and the seal 418. Thus, the asserted o-ring, and thus the engagement feature would be distal the asserted seal. Moreover, the asserted o-ring is not configured to connect with an instrument, but is instead spaced from any potential medical instrument. Specifically, the syringe 428 pushes against valve 418 to move it into the housing. (See, col. 12, ll. 60-63). Thus, the asserted o-ring is separated from any inserted instrument from the valve and cannot be the engagement feature.

The Office has further rejected claims 31-32 as obvious over Vailancourt or Lopez. As Vailancourt or Lopez do not show or describe the features of the independent claim from which claims 31 and 32 depend, they cannot form a *prima facie* case of obviousness against the dependent claims, as these claims incorporate the features of the base independent claim as well as recite additional features not shown or described by either Vailancourt or Lopez.

Dependent claims 33 and 42 also stand rejected as obvious in view of various combination of references. Without conceding the propriety of the asserted combinations, or the assertions made in the Office Action with respect to the allegedly disclosed subject matter, Applicant submits that each depends from a patentable independent claim 30, in view of the above, and is therefore patentable.

Favorable action is solicited, and a finding of patentability of claims 30-33, and 40-42 is respectfully requested.

Dated: November 23, 2009

Respectfully submitted,

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